



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-2873]

Workshop on Promoting Semantic Interoperability of Laboratory Data; Public Workshop;
Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Library of Medicine (NLM) of the National Institutes of Health (NIH), the Office of the National Coordinator for Health Information Technology (ONC), and the Centers for Medicare and Medicaid Services (CMS) are announcing the following public workshop entitled "CDC/FDA/NLM/ONC/CMS Workshop on Promoting Semantic Interoperability of Laboratory Data." The purpose of this public workshop is to receive and discuss input from stakeholders regarding proposed approaches to facilitate the adoption and implementation of interoperability standards in a manner that enables consistent, accurate, and harmonized descriptions of in vitro diagnostic tests and results.

DATES: The public workshop will be held on November 8, 2016, from 8 a.m. to 5 p.m. (EDT). Submit either electronic or written comments on the public workshop by December 9, 2016.

ADDRESSES: The public workshop will be held at the NLM NIH Bethesda Campus, 8600 Rockville Pike, NIH Building 38A, Bethesda, MD 20894. For general information, including parking and security information, please refer to:

https://www.nlm.nih.gov/about/lhcaud_gen.html.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information

submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-N-2873 for the "CDC/FDA/NLM/ONC/CMS Workshop on Promoting Semantic Interoperability of Laboratory Data." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m. EDT, Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR

56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Michael Waters, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4535, Silver Spring, MD 20993-0002, 301-796-4653, FAX: 301-847-2512, email: michael.waters@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

This public workshop is a followup to the FDA/CDC/NLM Workshop on "Promoting Semantic Interoperability of Laboratory Data" held on September 28, 2015. For more information on the content of the previous public workshop, the Webcast, the transcript, and any presentations from the 2015 workshop can be found at:

<http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm453897.htm>.

The primary purpose of the current workshop is to discuss with stakeholders the means to facilitate adoption and implementation of interoperability standards in a manner that enables consistent, accurate, and harmonized electronic health data reporting. Specifically this workshop will discuss aspects of semantic interoperability of laboratory data including the use of Logical Observation Identifiers Names and Codes (LOINC; <http://loinc.org/>) for identifying laboratory

tests and the use of Uniform Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT; <http://www.ihtsdo.org/snomed-ct>) coding sets for describing results of qualitative test results.

In order to build on the foundations of what was discussed during the 2015 workshop, discussions will begin by summarizing the previous workshop and addressing questions and concerns that were raised at the previous meeting. These conversations will be followed by a discussion on potential mechanisms for implementation of structured communication models containing device information, LOINC (<http://loinc.org/>), transmission codes, and other information that can be used to consolidate a semantically interoperable and transmittable message.

II. Topics for Discussion at the Public Workshop

This public workshop will consist of brief presentations to provide a framework and a context for a series of interactive panel discussions. Presentations will focus on mechanisms for attaining harmonized semantically interoperable information and advancing the probable functional models for information transmission, including possible challenges and solutions for implementation. Presentations and discussions will address proposals for harmonization and communication that can facilitate practical adoption of semantically interoperable data. Following the presentations on each topic, there will be a moderated discussion where the participants and additional panelists will be asked to provide their individual perspectives.

In advance of the meeting, CDC, FDA, NLM, ONC, and CMS will place an agenda on file in the public docket (the docket number found in brackets in the heading of this document) and will post it at

<http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. See DATES for the deadline for submitting comments to the agenda for the public workshop.

The agencies will use the input from this workshop and public comments to determine the appropriate next steps to advance semantic interoperability of laboratory data.

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m. (EDT) October 28, 2016. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 7 a.m. (EDT).

If you need special accommodations due to a disability, please contact Rebecca Goodwin at 301-496-4441 (Rebecca.Goodwin@nih.gov) and/or the Federal Relay at 1-800-877-8339. Requests should be made no later than November 3, 2016.

To register for the public workshop, please visit FDA's Medical Devices News & Events-Workshops & Conferences calendar at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. Those without Internet access should contact Michael Waters to register (see FOR FURTHER INFORMATION CONTACT). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be videocast. Videocast access will be available at <https://videocast.nih.gov/>. The videocast link

will also be available on the registration Web page. FDA has verified the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

Requests for Oral Presentations: This public workshop includes a public comment session. During online registration you may indicate if you wish to present during a public comment session, and which topics you wish to address. FDA has included general topics in this document. FDA will do its best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the public comment session. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by November 1, 2016. All requests to make oral presentations must be received by the close of registration on 4 p.m. (EDT) October 28, 2016. If selected for presentation, any presentation materials must be emailed to Michael Waters (see FOR FURTHER INFORMATION CONTACT) no later than October 28, 2016. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

CDC, FDA, NLM, ONC, and CMS are holding this public workshop to obtain input from stakeholders regarding proposed approaches to facilitate the adoption and implementation of interoperability standards in a manner that enables consistent, accurate, and harmonized electronic laboratory reporting. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the

public workshop topics. See DATES for the deadline for submitting comments to the agenda for the public workshop.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see ADDRESSES). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at <http://www.fda.gov>. A link to the transcript will also be available approximately 45 days after the public workshop on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list).

Dated: September 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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